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09/521,742    03/09/00    HAMMARSTROM    L    49122

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EXAMINER

HARRIS, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

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DATE MAILED:

06/07/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/521,742

Applicant(s)

Hammarstrom et al.

Examiner

Alana M. Harris, Ph. D.

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on April 2, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above, claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-46 are pending.

Claims 28 and 29 have been amended.

Claims 32-46 have been added.

Claims 1-27, drawn to non-elected inventions are withdrawn from examination.

Claims 28-46 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

3. The disclosure is no longer objected to because Applicants have ended the sentence on page 22, line 2 with a period.

### ***Maintained and New Rejections***

#### ***Claim Rejections - 35 U.S.C. § 112***

4. The rejection of claims 28-31 and newly added claims 32-46 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating malignant cancer cell lines such as those listed in Table 1 of the specification (page 26 ) comprising an

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enamel matrix derivative, namely EMDOGAIN®, does not reasonably provide enablement for a method for preventing or treating malignant or benign neoplasms, comprising administering to a mammal an active enamel substance is maintained and made. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and implement the invention commensurate in scope with these claims.

Applicants argue that the Examiner has not provided any substantiating reasons for her position and that the data of record is critiqued in support of the rejection, as well as the instant rejection appears premised on unsupported criticisms of Applicants' disclosure. Applicants also assert that "the present application fully satisfies the requirements of Section 112" and that the Examiner's citation of a 1975 document is not seen as particularly relevant. Applicants' arguments have been considered, but found unpersuasive.

At the onset of the rejection (paragraph 5, sections a-c) set forth in Paper number 6, mailed October 25, 2000 the Examiner noted that Applicants were enabled for a method for treating specific malignant cancer cell lines with enamel matrix derivative, EMDOGAIN® (EMD). Likewise, the Examiner also noted that this evidence contained within the specification was dubious given the fact that the disclosure provided no treatment of "normal" cell line counterparts. One skilled in the art would agree that the scientific basis of an experiment is the testing and observation of results between a set of normal samples versus diseased samples. Applicants have not provided information regarding what happens when the normal counterparts of the malignant cancer cell lines are treated with EMD, hence definitive conclusions cannot be

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made. Applicants point out that the application discloses the results for controls on "...page 25, lines 17-19, page 25, lines 6-7 and Figures 1-3 of the application." There are no lines past line 12 on page 25. Applicants have provided evidence of differing effects between Hela cells, as well as other malignant cells treated with EMD and without EMD how is one skilled in the art to know that the effect of EMD on these cells is any different from the non-diseased counterparts?

Applicants assert that the primary tissue cultures used in their experimentation are non-transformed cells and thus represent a system closely resembling *in vivo*. Applicants have not presented an animal model whereby the affects of EMD could be examined. One skilled in the art cannot reasonable conclude that the results yielded from an *in vitro* study could be extrapolated to an *in vivo* therapy. And while it is not compulsory upon Applicants to present data with absolute predictability with respect to the practice of every possible embodiment of a claimed invention the claims must be enabled. Applicants' broad claims read on the treatment of any and all malignant and benign neoplasms regardless of histology or grade. The Johnson and Goldin reference of 1975 cited in the first action on the merits is at least two decades old nevertheless the premise holds true at this point in prosecution of the instant application that one skilled in the art cannot use one treatment modality to medicate all tumors termed cancerous. Each cancer type requires different modes of therapy and the day has yet to come that treatment of all cancers is equilavent.

For the reasons set forth and in Paper #6 paragraph 5 the rejection is maintained. It would require undue experimentation of one of skill in the art to perform this broadly claimed method on an almost endless number of cancers of many, many different types.

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5. The rejection of claims 28-31 and newly added claims 32-46 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and made.

a. The recitation "...therapeutically effective amount of an active enamel substance." in claim 28 is vague and indefinite. It is noted Applicants have amended claim 28 to no longer recite "prophylactically", however there is know response seen in regards to what is deemed a therapeutically effective amount of an active enamel substance. This rejection is maintained for the reasons of record in paragraph 7(a) in Paper #6.

b. The recitation "affected tissue" in claim 29 is vague and indefinite. Applicants argue that this claim would be readily understood in view of the application as a whole. Applicants are reminded that the limitations of the specification cannot be read into the claims. The claims should be clearly written in a manner in which one skilled in the art immediately grasps what Applicant is indeed claiming. It is still not clear what deems a tissue "affected"? How would one skilled in the art be able to determine the metes and the bounds of the claim?

c. Claims 28-41 and 43 are vague and indefinite in the recitation "enamel substance" as the metes and bounds of the claim cannot be determined. Applicants argue "that the term is well understood, especially in view of the extensive disclosure of the application." This is found unpersuasive. A number of items are regarded as enamel substances. The claims containing this term must be definite as to allow the comparison with the available art and clear for the public to determine what the claims encompass.

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d. The recitation "...an active enamel substance." in claims 28-41 and 43 is vague and indefinite. This rejection is maintained and made for the reasons of record listed in paragraph 7(e). What qualifies the enamel substance active? What properties are bestowed upon the enamel substance?

e. Claims 30, 31 and 46 are vague and indefinite in the recitations "derivatives", "derivatives thereof" and "mixtures thereof". Applicants have not responded to this rejection made in Paper #6. It is maintained for the reasons set forth in paragraph 7(f).

6. Claims 28-46 are free of the art.

*Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
June 7, 2001

  
SHEELA HUFF  
PRIMARY EXAMINER